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Calyx RIM 7.0 Analytics with Power BI

CALYX™

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Analytics with Power BI

Analytics with Power BI provides a visual representation of Calyx RIM data.

The following reports are available for Calyx RIM:

Report Name	Description
Worldwide Registrations & Events Reports	The Worldwide Registrations & Events Reports supports the requirements for worldwide registrations with wider information formed in the PBI dashboards for marketed statuses, registration statuses, products, countries, different event types and event statuses. This report summarizes the Registrations, Events, and associated registered details. Dashboard can be filtered by products or countries and serves as a visual doorway into your RIM data.
Paginated Report - PSUR WMAS	The Paginated PSUR WMAS report shows the date of the first authorisation worldwide, indications(s), authorised dose(s), and parameters (where authorised). This report supports the requirements described in section VII.B. 5.2 PSUR section Worldwide marketing authorisation status of the EMA guideline on good pharmacovigilance practices (GVP) Module VII – Periodic safety update report.
Paginated Report - PSMF Annex H	The Paginated PSMF Annex H report shows region and country parameter marketing authorisation status. This report supports the requirements described in section II.B.4.8 Annex to the PSMF of the EMA guideline on good pharmacovigilance practices (GVP) Module II – Pharmacovigilance system master file to provide a list of medicinal products covered by the pharmacovigilance system master file.
Paginated Report - RMP	The Paginated RMP report shows product statuses in the countries. This report supports the requirements described in section Annex 3 - Worldwide marketing authorisation by country (including EEA) of the EMA guidelines document <i>Guidance on the format of the risk management plan (RMP) in the EU</i> .
Paginated Report - Associate Licenses Marketing Status	The Paginated Associate Licenses Marketing Status report shows the country parameter marketing authorisation status. The products licensed in [market X - For Example France] will not be licensed/marketed in ROW markets. Reporting such removals is a French and German (and possibly some others) regulatory requirement.
XEVMPD Status	The XEVMPD Status report displays XEVMPD data in PBI that includes entity information for Registrations, Full Product Presentations, QPPVs mapped to EU and EEA Countries, and EV Code and acknowledgment file availability.

Access Reports

You can access reports to view Calyx RIM activities.

Prerequisites

You must link Power BI system to Calyx RIM to access reports. See *Linked Systems* under Calyx RIM Administration > Technical Administration > Linked Systems.

To access Calyx RIM reports:

1. In the upper-right corner of the Calyx RIM application, click **Liquent InSight**.
2. Click the display name for Power BI that was used when configuring Power BI.
The Power BI reports application opens in a new browser tab.
3. If required to authenticate, use appropriate credentials and click **Sign in**.
The reports are listed.
4. Click a report name.
5. Select the necessary values in the filters and click **View Report**.

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